

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

IN RE STEMLINE THERAPEUTICS, INC.  
SECURITIES LITIGATION

Master File No. 1-17-CV-00832-PAC

**AMENDED CLASS ACTION  
COMPLAINT FOR VIOLATIONS OF  
FEDERAL SECURITIES LAWS**

**CLASS ACTION**

**JURY TRIAL DEMANDED**

THIS DOCUMENT RELATES TO: ALL ACTIONS

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Lead Plaintiffs Adam Ludlow, Daljit Singh, and Kenneth Walsh and Representative Plaintiff Marion Beeler (collectively, “Plaintiffs”), allege the following by and through their attorneys and on behalf of all other persons and entities similarly situated. All of the following allegations are made upon information and belief, except those allegations concerning Plaintiffs, which are alleged upon personal knowledge. Plaintiffs’ information and belief is based upon, among other things, their counsel’s investigation, which includes without limitation: (a) review and analysis of regulatory filings made by Stemline Therapeutics, Inc. (“Stemline” or the “Company”) with the United States Securities and Exchange Commission (“SEC”); (b) review and analysis of press releases and media reports issued by and disseminated by Stemline; (c) review of other publicly available information concerning Stemline; and (d) interviews with individuals with knowledge of Stemline’s clinical trials.

## **I. INTRODUCTION**

1. This is a class action on behalf of persons or entities who purchased or otherwise acquired Stemline securities: (1) pursuant and/or traceable to Stemline’s secondary public offering on or about January 20, 2017 (the “Offering”); and/or (2) on the open market between January 20, 2017 and February 1, 2017, inclusive (the “Class Period”). Plaintiffs seek to recover compensable damages caused by Defendants’ violations of the federal securities laws under the Securities Act of 1933 (the “Securities Act”) and under the Securities Exchange Act of 1934 (the “Exchange Act”).

2. Stemline develops and tests cancer drugs on humans. Stemline’s leading therapy is SL-401, a therapy to treat certain rare, deadly blood-related cancers, including blastic plasmacytoid dendritic cell neoplasm (“BPDCN”) and acute myeloid leukemia (“AML”). In a January 20, 2017 filing with the SEC, incorporating by reference annual reports on Form 10-K and quarterly reports on Form 10-Q, Stemline falsely stated that enhanced safety and dosage

protocols it had developed to combat a severe, life-threatening side-effect of SL-401, capillary leak syndrome (“CLS”), after the lead-in phase of the clinical trial, had eliminated any further CLS occurrence. Well before filing that document, however, Defendants knew that another study participant had contracted severe CLS, necessitating that the patient stop receiving SL-401. That study participant died days later.

3. During earlier, Phase 1 and 2 studies of SL-401, after two patients died of severe CLS, Stemline disclosed both the occurrences of the severe CLS in December 2015 and that the Company had implemented a new safety and dosage protocol in an attempt to eliminate severe CLS in study participants. Thereafter, over successive public disclosures, Stemline stated that after implementing the new safety and dosage protocol, no study participant had contracted severe CLS. A patient enrolled in the expansion phase of the Company’s SL-401 trial for BPCDN, another open-label, non-randomized study, began experiencing severe side effects on January 14, 2017, necessitating that her infusions be stopped. Despite the fact that stopping the infusion cycle was consistent with Stemline’s safety protocol, the patient was diagnosed with severe CLS on January 17, 2017, dying on January 18, 2017. Stemline learned about the patient’s death on that same day.

4. Two days later, on January 20, 2017, Stemline filed with the SEC a prospectus, offering of 4.5 million shares of its common stock at \$10 per share. The prospectus discussed SL-401 clinical trials, and both included and incorporated by reference information on the therapy’s safety and adverse side effect profile. Defendants stated that SL-401 had previously caused CLS during the safety and dosage lead-in phase on the Company’s clinical trial but that after Defendants implemented a new safety and dosage protocol, no more study participants had developed severe CLS. The prospectus omitted that a patient in the trial had actually developed

severe CLS just a few days earlier, long after Defendants seemed to have eliminated severe CLS with the enhanced dosage and safety protocols.

5. On February 2, 2017, before the market opened, *TheStreet.com* revealed that a study participant had died on January 18, 2017 after being diagnosed with severe CLS. Stemline issued a press release confirming that a patient in its SL-401 study had died after developing CLS, and admitting that it had received a report of the death on January 18, 2017. On this news, Stemline shares fell \$4.15 per share, to close at \$5.60 on February 2, 2017, or approximately 42.5% down from its previous closing price.

## **II. JURISDICTION AND VENUE**

6. The claims asserted herein arise under and pursuant to Sections 11 and 15 of the Securities Act (15 U.S.C. §§ 77k and 77o), and Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

7. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331, Section 22 of the Securities Act (15 U.S.C. § 77v), and Section 27 of the Exchange Act (15 U.S.C. § 78aa).

8. Venue is proper in this Judicial District pursuant to 28 U.S.C. § 1391(b) and Section 27 of the Exchange Act (15 U.S.C. § 78aa(c)). The Company and Defendant Jefferies are headquartered in this Judicial District, and a significant portion of Defendants' actions, and the subsequent damages, took place in this Judicial District.

9. In connection with the acts, conduct and other wrongs alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mails, interstate telephone communications and the facilities of the national securities exchange.

### III. PARTIES

10. Plaintiff Adam Ludlow, as set forth in the previously filed certification, incorporated by reference herein, purchased Stemline securities pursuant to the Company's Offering and/or during the Class Period and was economically damaged thereby.

11. Plaintiff Daljit Singh, as set forth in the previously filed certification, incorporated by reference herein, purchased Stemline securities pursuant and/or traceable to the Company's Offering and/or during the Class Period and was economically damaged thereby.

12. Plaintiff Kenneth Walsh, as set forth in the previously filed certification, incorporated by reference herein, purchased Stemline securities pursuant and/or traceable to the Company's Offering and/or during the Class Period and was economically damaged thereby.

13. Representative Plaintiff Marion Beeler, as set forth in the concurrently-filed certification, purchased Stemline securities pursuant to the Company's Offering and/or during the Class Period and was damaged thereby.

14. Defendant Stemline is a clinical stage biopharmaceutical company that focuses on the discovery, acquisition, development, and commercialization of proprietary oncology therapeutics in the United States. The Company is incorporated in Delaware. Its principal executive offices are located at 750 Lexington Avenue, Eleventh Floor, New York, New York 10022. Stemline's common stock is traded on The NASDAQ Capital Market ("NASDAQ") under the ticker symbol "STML."

15. Defendant Ivan Bergstein ("Bergstein") founded Stemline in August 2003 and has been its Chairman, Chief Executive Officer ("CEO") and President since August 2003.

16. Defendant Ron Bentsur ("Bentsur") is a Director of Stemline, a position he has held since 2009.

17. Defendant Eric L. Dobmeier (“Dobmeier”) is a Director of Stemline, a position he has held since 2012.

18. Defendant Alan Forman (“Forman”) is a Director of Stemline, a position he has held since 2012.

19. Defendant David Gionco (“Gionco”) has been the Chief Accounting Officer and Vice President of Finance of Stemline since December 16, 2013 and January 16, 2014, respectively.

20. Defendant Kenneth Zuerblis (“Zuerblis”) is a Director of Stemline, a position he has held since 2012.

21. Defendants Bergstein, Bentsur, Dobmeier, Forman, Gionco and Zuerblis are collectively referred to herein as the “Individual Defendants.”

22. Defendant Jefferies LLC (“Jefferies”) was the lead underwriter of Stemline’s secondary offering of securities on January 20, 2017.

23. Defendants Stemline, Jefferies, and the Individual Defendants are collectively referred to herein as “Defendants.”

#### **IV. SUBSTANTIVE ALLEGATIONS**

##### **A. Background**

##### **1. Overview of Clinical Trial Development and Special Status**

24. Development of a new drug occurs in stages. After the discovery of a potentially helpful compound, researchers carry out studies to determine whether tests on human beings are warranted. If the new drug is sufficiently promising, the FDA will approve it for clinical trials, *i.e.*, tests on human subjects. Stemline develops oncology drugs at the clinical stage.

25. The clinical stage involves two or more stages of testing on human subjects. In the first stage of a clinical trial (sometimes called the “lead-in” stage), developers administer the

drug to a small number of individuals to determine how the treatment should be delivered and what constitutes an appropriate dosage of the drug. In the second stage (sometimes called the “expansion” stage), the drug developers expand the number of human subjects to be tested and attempt to determine whether the administered drug has an effect on the target disease or disorder. In the third stage, drug developers compare the new treatment with the current standard treatment to determine any benefits it may hold over the standard treatment. Sometimes researchers will combine two stages in designing the drug trials in order to streamline the research process; such combined stages are called “stage 1/2” or “stage 2/3” trials.

26. Clinical trials can be randomized or non-randomized. A randomized trial has two groups, the group receiving the treatment being tested and a control group receiving either standard or placebo treatments. The study randomly allocates participants to one of the groups. In an “open-label” non-randomized study, however, researchers and patients know which study participant receives treatment.

27. Clinical trials, whether randomized or non-randomized, are either blinded or open-label. In a blinded trial, patients and sometimes researchers (depending on whether the trial is single or double blinded) do not know if they are in the group receiving the experimental treatment. In an open-label clinical trial, both the researchers and participants know which treatment is being administered.

28. “Orphan Drug” status is a special status conferred by the FDA to a drug or biological product intended to treat a rare disease or condition. Intended to encourage research and development for rare diseases, an Orphan Drug designation qualifies the sponsor of the drug for various development incentives, including tax credits for qualified clinical testing. The granting of an orphan designation request does not alter the standard regulatory requirements and



process for obtaining marketing approval; rather, as with a standard approval track, safety and effectiveness of a drug must be established through adequate and well-controlled studies.

29. Breakthrough Therapy Designation (“BTD”) status may be conferred by the FDA upon a drug or therapy that the developer intends “alone or in combination with one or more other drugs to treat a serious or life threatening disease or condition and” where it has found “preliminary clinical evidence indicat[ing] that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development.” The FDA will expedite the development and review of BTD drugs. According to the FDA, BTD status provides for “more intensive FDA guidance on an efficient drug development program, an organizational commitment involving senior managers, and eligibility for rolling review and priority review.” As with Orphan Drugs, however, FDA review and approval standards are not relaxed under the BTD approval path; rather, drugs or therapies developed under BTD status must still demonstrate safety and effectiveness through adequate and well-controlled studies. However, BTD status may mean that the developer would have to enroll fewer patients in a clinical trial leading to approval, since the FDA would work closely with the trial sponsor to create a maximally efficient study design, which can translate to fewer patients enrolled in trials that ultimately support marketing approval.

## **2. The Development of SL-401**

30. Stemline is currently developing three therapies, but analysts consider SL-401 its leading drug candidate and the key value driver for the Company. SL-401 is a targeted therapy directed to the interleukin-3 receptor present on a wide range of malignancies, and Stemline is developing the drug as a therapy for blood-related cancers. It is currently carrying out a Phase 2 trial with patients with BPDCN as well as Phase 2 ongoing trials for patients with AML in

remission with minimal residual disease (“MRD”) and advanced, high risk myeloproliferative neoplasms (“MPN”) of unmet medical need. Stemline is also enrolling patients in a Phase 1/2 trial of SL-401 relapsed/refractory multiple myeloma, which combines the experimental therapy with standard therapies.

31. SL-401 works by exploiting the expression of the interleukin-3 receptor on cancerous cells. When SL-401 comes into contact with the receptor, the cell internalizes SL-401. Once inside the cell, SL-401 releases its payload, a diphtheria toxin that kills the cancer cell by inhibiting protein synthesis within that cell, which the cell needs to survive.

32. Stemline claims that SL-401 may be superior to other therapies for blood-related cancers because it targets cancerous cells, which have many more interleukin-3 receptors than normal cells.

33. On June 10, 2013, Stemline announced that SL-401 received Orphan Drug designation from the FDA for the treatment of BPDCN, a rare blood cancer with no approved therapies and limited treatment options.

34. On December 3, 2013, *The Street* reported that Stemline made misleading edits to patient anecdotes about SL-401 in its investor pitch. At the time, the Company’s presentation to potential investors included a slide containing message board posts from the website of the Leukemia and Lymphoma Society. Stemline presented quotes from spouses of two patients who were treated with SL-401 and reported that the patients had complete responses to treatment. However, Stemline edited those posts in a misleading way, omitting information about other, additional treatment, which might have suggested that other therapy was at least partially responsible for the patients’ responses to treatment. Stemline also issued a press release claiming that one of the patients who posted experienced no “serious side effects” following treatment with

SL-401, but the patient's own blog described treatment with the drug as "difficult and unpredictable" with "harsh side effects" that required a prolonged hospital stay. In response, the Leukemia and Lymphoma Society stated that it asked Stemline to reconsider the use of the posts in its investor deck.

35. On May 23, 2014, a team of researchers, including Defendants Bergstein and Stemline employees Christopher Brooks, Michael Szarek, and Eric Rowinsky published the results of the first prospective study of treatment of patients with BPDCN with SL-401 online in the medical journal *Blood*.<sup>1</sup> This BPDCN study represented an expansion arm of a phase 1-2 trial of SL-401 in patients with advanced hematologic malignancies. Eleven patients were treated with 14 courses of SL-401. All were evaluated for safety and nine were evaluable for objective response to SL-401. Of those nine patients, seven showed major responses to the drug, including five complete responses and two partial responses after a single course of SL-401. Significantly, the article stated that "[a]ll treatment-related [adverse events] were brief and resolved completely." The article also noted that "There were no treatment related deaths."

36. After the early success in this trial, on July 28, 2014, Stemline announced the opening of its broad clinical development program for SL-401. The Company initiated a corporate-sponsored multicenter, open-label, non-randomized trial in patients with BPDCN and relapsed/refractory AML, which was designed to accrue at least 60 patients (the "Pivotal Trial"). The Pivotal Trial opened with a lead-in phase (the "Lead-In Phase"), in which the Company would evaluate dosage and safety before beginning an expansion phase (the "Expansion Phase").

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<sup>1</sup> Arthur Frankel, et al., *Activity of SL-401, A Targeted Therapy Directed to Interleukin-3 Receptor in Blastic Plasmacytoid Dendritic Cell Neoplasm Patients*, 124 *Blood* 385 (July 17, 2014) (pre-published online May 23, 2014).

37. During the Lead-In Phase, which was completed on June 30, 2015, two patients died from severe CLS related to their receiving SL-401.

38. CLS is an extremely serious side effect of SL-401. CLS occurs when the thin layer of endothelial cells that line the walls of a person's capillaries – the smallest of the body's blood vessels – separate, allowing fluid from the circulatory system to leak into the interstitial space. CLS has extremely serious consequences, including perilously low blood pressure (hypotension), a significant increase in the concentration of red blood and a decrease in plasma volume in the blood (hemoconcentration), and a sharp decrease in the protein that makes up plasma, albumin (hypoalbuminemia). Together, these effects limit the normal circulation of blood in the body. Patients with CLS experience swelling and dramatic drops in blood pressure that can cause organ failure. CLS is a devastating and life threatening side effect – the kind of side effect that could derail the approval of otherwise effective experimental therapies if it cannot be controlled.

39. On December 7, 2015, Stemline reported the results of its Lead-In Phase of the Pivotal Trial. After reporting efficacy information, Stemline presented data regarding the safety of SL-401 as follows:

**Table 2. Overview of SL-401 Safety in BPDCN****Most common adverse events (AEs) ( $\geq 15\%$ ; treatment-related)**

	Treatment-related AEs		All AEs	
	All grades	grade $\geq 3$	All grades	grade $\geq 3$
Transaminase elevation	64%	43%	71%	43%
Hypoalbuminemia	46%	0%	54%	4%
Pyrexia	39%	0%	54%	7%
Nausea	36%	0%	46%	0%
Fatigue	32%	4%	43%	7%
Anemia	29%	25%	39%	29%
Thrombocytopenia	25%	21%	29%	25%
Chills	25%	0%	29%	0%
Decreased appetite	25%	0%	25%	0%
Hypotension	21%	0%	29%	7%
Edema peripheral	21%	0%	25%	0%
Weight increased	18%	0%	25%	0%
Lymphopenia	18%	14%	18%	14%
Capillary leak syndrome (CLS)	18%	11%	18%	11%

**Dose levels, DLTs, and adjustments made in Lead-in (Stage 1)**

- Cohort 1 (7 ug/kg/day): grade 5 CLS (BPDCN); cohort expanded to 6 patients and cleared
- Cohort 2 (9 ug/kg/day): no DLTs (n=3 patients); cohort cleared
- Cohort 3 (12 ug/kg/day): grade 4 CLS (BPDCN); cohort expanded to 6 patients and cleared

Note: Since implementation of the following safety precautions, severe CLS has not been observed at doses up to 12 ug/kg/day (n >10 patients): normal cardiac ejection fraction (LVEF) required at study entry; albumin of  $\geq 3.2$  g/dL required at study entry; if weight gain >1.5 kg from prior day, SL-401 held for  $\geq 1$  day until stable; if albumin reduction to <3.0 g/dL or absolute reduction of 1.0 g/dL from pre-cycle baseline, SL-401 withheld for remainder of cycle (but may resume at next cycle); if transaminase elevation >5x ULN, SL-401 withheld for remainder of cycle (but may resume at next cycle).

- Cohort 4 (16 ug/kg/day): grade 5 suspected CLS (AML r/r); cohort expanded to 6 patients
- Cohort 4 (16 ug/kg/day): grade 3 infusion reaction (AML r/r); DLT in AML (r/r) in this cohort

**Dose and schedule determined for expansion (Stage 2)**

- BPDCN: 12 ug/kg/day (MTD not reached)
- AML (r/r): 12 ug/kg/day (MTD)

40. In layman's terms, a grade 5 CLS means patient death. These results indicated, in medical language, that SL-401 caused grade 3 or higher CLS in three patients, killing two and causing a life-threatening emergency in a third. One BPDCN patient and one AML patient died of CLS caused by SL-401 during the Lead-In Phase.

41. Normally, a drug causing such a serious side effect would likely be pulled from development. However, Stemline implemented a safety protocol aimed at minimizing the likelihood of CLS that appeared – at least temporarily – to solve the problem. Stemline has reported that since it adopted protocols requiring normal cardiac ejection fraction at study entry, requiring a specific level of albumin at study entry, and carefully monitoring and responding

based on patient weight gain, albumin reduction, and transaminase elevation, no more severe CLS had been observed at doses up to 12/ug/kg/day.<sup>2</sup>

42. Stemline began the Expansion Phase of the Pivotal Trial during the second quarter of 2015.<sup>3</sup> The Company intends to make a marketing application to the FDA on the basis of the results of the Pivotal Trial in the second half of this year.

43. Included in the trial was study OSU-13247 at the James Cancer Hospital (“JCH”) of Ohio State University, in Columbus, Ohio. JCH describes the study as “SL-401 in Patients With Blastic Plasmacytoid Dendritic Cell Neoplasm or Acute Myeloid Leukemia” It further described the study, stating:

“This is a non-randomized, open-label, multi center study. A cycle of therapy is 5 consecutive days every 21 days for 6 or more cycles. Stage I will consist of a brief run-in period in which patients with BPDCN (previously untreated and previously treated) and AML (persistent/recurrent and previously untreated) will be treated with SL-401 at 3 dose levels. During Stage 2, two cohorts of BPDCN and AML patients will be treated at the maximum tolerated dose or maximum tested dose in which multiple dose-limiting toxicities are not observed (identified in Stage 1).”

44. On June 8, 2016, Defendant Bregstein spoke at the Jefferies Healthcare Conference. He discussed the Company’s plans for the Expansion Phase of the Pivotal Trial as well as the side effect profile of SL-401. Bregstein said:

We've also had, early on in the study, something known as capillary leak syndrome, which is a fluid retention syndrome. We have instituted some preemptive measures around that, really a vigilance around the albumin levels. In some cases, if albumin drops below 3, it's usually a warning sign that fluid retention is coming. What we've done is -- and this is again typically a cycle one phenomenon -- if we withhold dosing in cycle one, virtually every case of that patient has been able to resume full dosing in cycle 2, and has not

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<sup>2</sup> Stemline Therapeutics, Inc., Current Report (Form 8-K) (Dec. 7, 2015).

<sup>3</sup> Stemline Therapeutics, Inc., Quarterly Report (Form 10-Q) (Aug. 10, 2015).

been an issue. And knock on wood, we have not had a case of severe capillary leak in a very long time, not since the lead-in stage of the study.

45. In August 2016, the FDA granted SL-401 BTD status based on data from the BCPDN trial, which is demonstrating high overall response rates, with multiple complete responses.

46. Both orphan drug status and BTD status are offering tremendous advantages to Stemline in its development of SL-401, through financial incentives as well as additional guidance and higher priority status during the approval process. The possibility of priority review as a BTD therapy would be especially helpful, because the FDA would likely take action on a marketing application within 6 months rather than the 10 month goal for action under standard review.

47. On January 6, 2017, Stemline announced an agreement with the FDA on the registration pathway for SL-401 in the treatment of BPDCN. Stemline also stated that it was enrolling an additional small cohort, planned to be 8-12 first-line BPDCN patients, into the ongoing Pivotal Trial to support the filing of a Biologics License Application for full approval in first-line BPDCN treatment, which would request permission to introduce SL-401 into interstate commerce.

### **3. Stemline's Safety Measures Fail**

48. On or about January 14, 2017, a BPDCN patient ("Patient") enrolled in the Expansion Phase of the Pivotal Trial at the James Cancer Center developed serious side effects. Patient was eventually diagnosed with CLS after receiving two treatments of a five treatment cycle that began on January 13, 2017 and was discontinued on January 14, after the second infusion, consistent with the safety and dosage protocol developed by Stemline after patients experienced CLS during the Lead-In Phase. On January 18, 2017, Patient died.

49. Stemline learned of Patient's death on the same day, and likely learned that Patient was experiencing severe side effects as soon as they occurred. As an investigational new drug, SL-401 is subject to the reporting requirements of 21 C.F.F. § 312.32, IND Safety Reporting. This means that Stemline is required to notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction as soon as possible, but in no case later than 7 calendar days after it learns of such a reaction. The investigators directly treating patients—who are mostly not employed by Stemline—are also required to submit safety reports directly to the FDA for any serious and unexpected adverse events.<sup>4</sup> These reporting standards make clear that life-threatening reactions are to be reported promptly, and if Stemline and the investigators followed them, the Company would have learned that a patient in the Pivotal Study had become extremely ill as soon as the patient's symptoms became serious.

**B. Defendants' False and Misleading Statements and Omissions**

50. On January 19, 2017, the day after Patient's death, Stemline announced a secondary public offering of its common stock (the "Offering") to fund, among other things, the potential commercialization of SL-401.

51. On January 20, 2017, Stemline commenced the Offering of 4.5 million shares of its common stock at \$10.00 per share, with expected gross proceeds to Stemline of \$45 million.

52. Also on January 20, 2017, Stemline filed a Form 424B5 with the SEC, containing Stemline's Prospectus Supplement, dated January 20, 2017, for the Offering (the "Prospectus" and together with the Registration Statement, the "Offering Documents").

53. In the Prospectus, Stemline described in detail its prior and current trials of SL-401, including the Pivotal Trial. Stemline did not, however, disclose that a patient had recently

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<sup>4</sup> Stemline Therapeutics, Inc., Annual Report (Form 10-K) (Mar. 14, 2016).



been diagnosed with CLS and died, after the implementation of its new safety measures and dosing guidelines. As a result, Stemline's Prospectus misled the investing public to believe that no additional severe CLS had occurred in the Pivotal Trial

54. The Prospectus expressly incorporated by reference, among other SEC filings, Stemline's Annual Report filed on Form 10-K on March 14, 2016 for the fiscal year ended December 31, 2015 (the "2015 10-K"), its Quarterly Report filed on Form 10-Q on November 8, 2016 for the quarter ended September 30, 2016 (the "2016 Q3 10-Q"), its Quarterly Report filed on Form 10-Q on August 8, 2016 for the quarter ended June 30, 2016 (the "2016 Q2 10-Q"), its Quarterly Report filed on Form 10-Q on May 9, 2016 for the quarter ended March 31, 2016 (the "2016 Q1 10-Q"), and its Current Report filed on Form 8-K on June 6, 2016 (the "June 6, 2016 8-K").

55. The 2015 10-K stated:

In terms of safety, multiple consecutive cycles of SL-401 dosed up to 12 ug/kg/day demonstrated a manageable safety and tolerability profile, with no evidence of cumulative side effects over multiple cycles. Additionally, we developed dosing and safety parameters during the lead-in stage of the study that were designed to minimize the risk of severe capillary leak syndrome (CLS). Since implementation of these measures, severe CLS has not been observed at doses up to 12 ug/kg/day.

56. This statement was false and misleading because Defendants knew or were reckless in not knowing that on January 14, 2017, a study participant in the Pivotal Trial, suffering from BPDCN and receiving a dose of SL-401 no greater than 12/ug/kg/day had developed severe CLS, necessitating that doctors cease treating that patient with SL-401. Defendants knew, too, that that study participant died on January 18, 2018.

57. The 2015 10-K also presented the following table presenting the most common adverse events related to SL-401:

**Table 2. Overview of SL-401 Safety in BPDCN****Most common adverse events (AEs) ( $\geq 15\%$ ; treatment-related)**

	Treatment-related AEs		All AEs	
	All grades	grade $\geq 3$	All grades	grade $\geq 3$
Transaminase elevation	64%	43%	71%	43%
Hypoalbuminemia	46%	0%	54%	4%
Pyrexia	39%	0%	54%	7%
Nausea	36%	0%	46%	0%
Fatigue	32%	4%	43%	7%
Anemia	29%	25%	39%	29%
Thrombocytopenia	25%	21%	29%	25%
Chills	25%	0%	29%	0%
Decreased appetite	25%	0%	25%	0%
Hypotension	21%	0%	29%	7%
Edema peripheral	21%	0%	25%	0%
Weight increased	18%	0%	25%	0%
Lymphopenia	18%	14%	18%	14%
Capillary leak syndrome (CLS)	18%	11%	18%	11%

**Dose levels, DLTs, and adjustments made in Lead-in (Stage 1)**

- Cohort 1 (7 ug/kg/day): grade 5 CLS (BPDCN); cohort expanded to 6 patients and cleared
- Cohort 2 (9 ug/kg/day): no DLTs (n=3 patients); cohort cleared
- Cohort 3 (12 ug/kg/day): grade 4 CLS (BPDCN); cohort expanded to 6 patients and cleared

Note: Since implementation of the following safety precautions, severe CLS has not been observed at doses up to 12 ug/kg/day (n >10 patients): normal cardiac ejection fraction (LVEF) required at study entry; albumin of  $\geq 3.2$  g/dL required at study entry; if weight gain >1.5 kg from prior day, SL-401 held for  $\geq 1$  day until stable; if albumin reduction to <3.0 g/dL or absolute reduction of 1.0 g/dL from pre-cycle baseline, SL-401 withheld for remainder of cycle (but may resume at next cycle); if transaminase elevation >5x ULN, SL-401 withheld for remainder of cycle (but may resume at next cycle).

- Cohort 4 (16 ug/kg/day): grade 5 suspected CLS (AML r/r); cohort expanded to 6 patients
- Cohort 4 (16 ug/kg/day): grade 3 infusion reaction (AML r/r); DLT in AML (r/r) in this cohort

**Dose and schedule determined for expansion (Stage 2)**

- BPDCN: 12 ug/kg/day (MTD not reached)
- AML (r/r): 12 ug/kg/day (MTD)

58. This statement was false and misleading because Defendants knew or were reckless in not knowing that on January 14, 2017, a study participant in the Pivotal Trial, suffering from BPDCN and receiving a dose of SL-401 no greater than 12/ug/kg/day had developed severe CLS, necessitating that doctors cease treating that patient with SL-401. Defendants knew, too, that that study participant died on January 18, 2018. In addition, the data Defendants presented in this chart failed to disclose that the percentage of severe CLS events rose due to the January 14, 2017 diagnosis.

59. In the 2016 Q2 10-Q, Stemline described the safety profile of BPDCN treatment with SL-401 in the Pivotal Trial as “continu[ing] to remain manageable over increasing treatment

duration, drug exposure, and patient experience, *with no new adverse events noted over time.*” (Emphasis added.)

60. This statement was false and misleading because Defendants knew or were reckless in not knowing that on January 14, 2017, a study participant in the Pivotal Trial, suffering from BPDCN and receiving a dose of SL-401 no greater than 12/ug/kg/day had developed severe CLS, necessitating that doctors cease treating that patient with SL-401. Defendants knew, too, that that study participant died on January 18, 2017.

61. In the June 6, 2016 8-K, Stemline filed with the SEC a press release announcing the presentation of clinical data from the BCPDN Pivotal Trial at the 2016 American Society of Clinical Oncology (ASCO) Annual Meeting. Naveen Pemmaraju, M.D. from the University of Texas MD Anderson Cancer Center, an investigator in the Pivotal Trial, presented that “[s]ince implementation of [the dosing and safety parameters developed in the Lead-In Phase], SL-401 at doses of 12 ug/kg/day has demonstrated a manageable safety and tolerability profile.”

62. This statement was false and misleading because Defendants knew or were reckless in not knowing that on January 14, 2017, a study participant in the Pivotal Trial, suffering from BPDCN and receiving a dose of SL-401 no greater than 12/ug/kg/day had developed severe CLS, necessitating that doctors cease treating that patient with SL-401. Defendants knew, too, that that study participant died on January 18, 2017.

63. The June 6, 2016 8-K also included a table titled “Overview of SL-401 Safety in BPDCN” that listed the most common adverse events associated with the therapy and each adverse event’s occurrence rate:

Table 2. Overview of SL-401 Safety in BPDCN

	All Grades (%)		Grade ≥ 3 (%)	
	TRAEs	All AEs	TRAEs	All AEs
Transaminase elevation	61	74	57	61
Hypoalbuminemia	43	48	0	0
Chills	35	39	0	0
Pyrexia	30	48	0	0
Nausea	26	52	0	0
Fatigue	26	43	0	9
Thrombocytopenia	22	22	22	22
Hypotension	22	22	0	0
Weight increased	22	30	0	0
Capillary leak syndrome	22	22	9	9
Anemia	17	30	13	17
Decreased appetite	17	22	0	0
Edema peripheral	17	43	0	0

Source: ASCO, 2016

## About Stemline Therapeutics

64. This statement was false and misleading because Defendants knew or were reckless in not knowing that on January 14, 2017, a study participant in the Pivotal Trial, suffering from BPDCN and receiving a dose of SL-401 no greater than 12/ug/kg/day had developed severe CLS, necessitating that doctors cease treating that patient with SL-401. Defendants knew, too, that that study participant died on January 18, 2017.

65. In addition to the statements incorporated by reference, the Prospectus included new statements that were false and misleading. In its discussion of the Pivotal Trial in the Prospectus, Stemline doubled down on its reference to Dr. Pemmaraju's statement that SL-401's safety profile was manageable, stating that "SL-401's safety profile has continued to remain predictable and manageable over increasing treatment duration, drug exposure, and patient experience." This statement was materially false and misleading. In fact, SL-401's safety profile was unpredictable, given that a patient developed severe CLS after the implementation of safety and dosage protocols that Stemline repeatedly stated were effectively preventing any additional severe CLS occurrences.

66. The Prospectus also touted SL-401's favorable clinical data as of the date of the Prospectus, January 20, 2017, noting "favorable clinical data observed to date with SL-401." This statement likewise was materially false and/or misleading because Stemline omitted the

information that a patient developed severe CLS after the implementation of safety and dosage protocols that Stemline repeatedly stated were effectively preventing any additional severe CLS occurrences, a development that could cause the termination of a clinical trial.

### C. The Truth Emerges

67. On February 2, 2017, before the market opened, *The Street* published an article entitled “Side Effect Kills Cancer Patient in Stemline Therapeutics Drug Trial, the Company Raises Money.” The article revealed that on January 18, 2017, two days prior to Stemline’s Offering, a cancer patient in an SL-401 clinical trial died from a severe side effect. The article stated, in part:

Investors who bought into a \$45 million Stemline Therapeutics (STML) stock offering on Jan. 19 were not told that one day prior to the financing, a cancer patient in a clinical trial died from a severe side effect, a type of low blood pressure, tied to the company’s drug SL-401.

[. . .]

The third death in Stemline’s SL-401 study due to capillary leak syndrome, not yet reported by the company but confirmed by a member of the patient’s family, is potentially troubling because it occurred after Stemline had already increased safety monitoring and added new dosing rules to reduce the incidence and severity of the side effect.

[. . .]

The patient received the first two doses of SL-401 on Jan. 12 and 13. Her third daily infusion was postponed because of deteriorating health due to side effects. **On Jan. 17, the patient was diagnosed with capillary leak syndrome. She died the next day, never having received three of the scheduled five doses of SL-401 in the initial treatment cycle of the clinical trial.**

[. . .]

During the dose-ranging stage of the phase II study, Stemline implemented additional safety precautions to reduce the risk of capillary leak syndrome before enrolling additional BPDCN patients into the expansion stage of the study.

The extra safety vigilance appeared to be working. When Stemline last presented interim results from the SL-401 phase II study in December at the American Society of Hematology annual meeting, none of the subsequently enrolled BPDCN patients had experienced severe (worse than grade 2) capillary leak syndrome.

**But that clean safety streak ended with the death of the BPDCN patient on Jan. 18, raising concerns that Stemline may not have the risk of fatal capillary leak syndrome under control.**

(Emphases added.)

68. On February 2, 2017, Stemline issued a press release entitled “Stemline Therapeutics Provides Update on Pivotal BPDCN Trial.” The Company confirmed the Patient’s death and admitted that it received a report of the death on January 18, 2017 and that the patient had developed CLS. The press release stated, in relevant part:

**On January 18, the Company received a report that a patient death had occurred. The patient had developed capillary leak syndrome (CLS), a known, sometimes fatal, and well-documented side effect of SL-401.** The cause of the patient’s death has not yet been determined. The safety profile for SL-401 includes CLS, and there have been previous deaths reported in patients with CLS in this trial, which have been disclosed in public presentations. That CLS is an expected complication of the administration of SL-401 has also been identified in filings with the Securities and Exchange Commission (SEC) and U.S. Food and Drug Administration (FDA), as well as in the study’s informed consent forms and other information provided to investigators. (Emphases added.)

69. On this news, Stemline’s share price fell \$4.15, or approximately 42.5%, to close at \$5.60 on February 2, 2017, damaging investors.

70. Throughout the Class Period, the price of the Company’s securities was artificially inflated as a result of Defendants’ materially false and misleading statements and omissions identified herein. Defendants’ wrongful conduct, as alleged herein, directly and proximately caused the economic loss suffered by Plaintiffs and the Class.

71. The price of the Company's securities significantly declined when the misrepresentations made to the market, and/or the information alleged herein to have been concealed from the market, and/or the effects thereof, were revealed, causing investors' losses.

**D. Additional Scienter Allegations**

72. On February 2, 2017, Stemline issued a press release in which it stated simply that, "On January 18, the Company received a report that a patient death had occurred. The patient had developed capillary leak syndrome (CLS), a known, sometimes fatal, and well-documented side effect of SL-401."

73. Defendants, however, were aware of more information about the patient they described in their February 2, 2017 press release. For example, according to Patient's family, investigators at JCH administered the first dose of SL-401 (of a five-dose cycle) on January 12, 2017. On the second day, the JCH doctors administered the second SL-401 treatment after finding no negative side effects from the first administration of SL-401. On January 14, 2017, the JCH doctors postponed the third administration of SL-401 because Patient had what staff described to patient as "minor fluctuations in vitals and labs that hospital staff would like to stability before proceeding with any more treatments."

74. By January 16, 2017, Patient's family reported that the JCH doctors had suspended further treatment because Patient was "experiencing some dangerous side effects from the SL-401." On January 17, 2017, Patient's family reported that Patient would not complete SL-401 treatments as "she was diagnosed with Capillary Leak Syndrome, which is a known side effect of SL-401. This syndrome," Patient's family reported, "caused severe hypotension, tachycardia, sever edema, as well as severely high lactate dehydrogenase, potassium, WBC, RBC, HGB, hemocrit, grans, monos, monocytes, and severely low lymphs, platelets, and albumin." Patient's family further described that "[a]fter battling this for 3 days, today [Patient's] labs are normal and

the dangerous side effects have subsided. The medical team at OSUCCC-James Cancer Hospital and Solve Research Institute worked tirelessly and continuously to get her out of danger and bring her back to health.”

75. On February 3, 2017, Patient’s family reported that patient had died at 6:08am on January 18, 2017. Defendants filed the final Prospectus Supplement, selling 4.5 million shares to the market on January 20, 2017 at 4:03pm. Patient’s family described that Patient “was suffering from Capillary Leak Syndrome, a side effect of SL-401.” As of Patient’s family’s last update, doctors were “awaiting results from the microscopic perspective” from the autopsy to determine a cause of death.

76. As Defendants themselves conceded in their February 2, 2017, press release, they were made aware of the patient death the same day the death occurred, on January 18, 2017. Then, on January 20, 2017 at 4:03pm, Defendants filed the final Prospectus Supplement, offering 4.5 million shares of Stemline securities for sale to the market, without disclosing the material adverse event that had occurred only two days earlier.

77. Moreover, after the market learned of the January, 2017 case of severe CLS and subsequent death, Defendants, themselves, changed the words they used to describe the incidents of CLS patients in the studies had experienced. For example, in their 2015 10-K, about “treatment-related reported adverse events,” Defendants had stated:

In terms of safety, multiple consecutive cycles of SL-401 dosed up to 12 ug/kg/day demonstrated a manageable safety and tolerability profile, with no evidence of cumulative side effects over multiple cycles. Additionally, we developed dosing and safety parameters during the lead-in stage of the study that were designed to minimize the risk of severe capillary leak syndrome (CLS). Since implementation of these measures, severe CLS has not been observed at doses up to 12 ug/kg/day. Most common treatment related adverse events, all grades, were transaminase elevation



(64%) and hypoalbuminemia (46%). Thrombocytopenia was also noted (25%).

78. In their 2016 10-K, however, Defendants altered that language to disclose more clearly the adverse events, including by specifically identifying patient deaths, stating:

The most commonly reported > grade 3 treatment-related reported adverse events were transaminase elevation (40%) and thrombocytopenia (19%) in BPDCN patients. Safety precautions, including daily monitoring of albumin and body weight during study drug infusions, have been implemented in an attempt to reduce the risk of severe capillary leak syndrome, or CLS. As of the 2016 ASH annual meeting, two patients had a ***grade 5 (i.e., patient death) drug-related CLS***: one BPDCN patient (7 ug/kg, Stage 1) and one r/r AML patient (16 ug/kg, Stage 1), the former dosed prior to implementation of the aforementioned safety precautions and the latter dosed at the 16 ug/kg level — a dose higher than is currently used. ***Subsequent to the ASH meeting, in January 2017 there was an additional grade 5 event relating to CLS*** that occurred in a BPDCN patient (12 ug/kg, Stage 3), a case that is open and being evaluated.

(Emphasis added.)

79. Defendant Bergstein served as CEO and Director of Stemline throughout the Class Period. Defendants Bentsur, Dobmeier, Forman, and Zuerblis also served as Directors of Stemline throughout the Class Period. Defendant Gionco served as Chief Accounting Officer and Vice President of Finance throughout the Class Period.

80. As CEO, Bergstein was the head of Stemline's management team, and Defendants Bentsur, Dobmeier, Forman, and Zuerblis likewise had global responsibilities over the operations of Stemline. Bergstein, by virtue of his responsibilities and activities as CEO and Director of the Company, Gionco as Chief Accounting Officer and Vice President of Finance, and Bentsur, Dobmeier, Forman, and Zuerblis, as Directors, were privy to all material information concerning the core of Stemline's business, which was the development of three drugs, including SL-401, through testing them on human subjects. Bergstein had knowledge of critical adverse events,

including patient deaths, resulting from clinical trials of Stemline's drugs, because these clinical trials directly impacted the viability of one of Stemline's (three) potential drugs, and therewith, its core business.

81. Likewise, Gionco, as Chief Accounting Officer, was privy to, and participated in, all matters directly impacting the financial aspects of Stemline's core business, including critical adverse events like patient deaths resulting from clinical trials of Stemline's drugs.

82. Defendants Bergstein and Gionco each signed a certification pursuant to the Sarbanes-Oxley Act of 2002 ("SOX") for each SEC filing referenced in Part VI above during his or her tenure as CEO or CFO. In these certifications, each of the Individual Defendants certified that he or she had reviewed the SEC filings and determined that they contained no false or misleading statements or omissions.

83. By virtue of their high-level positions, Individual Defendants' knowledge may be imputed to Stemline.

## **V. CLASS ACTION ALLEGATIONS**

84. Plaintiffs bring this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a class, consisting of all persons or entities that acquired Stemline securities during the Class Period and who were damaged thereby (the "Class"). Excluded from the Class are Defendants, the officers and directors of the Company at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

85. In addition to being a representative plaintiff for the Class, Plaintiff Marion Beeler is the representative plaintiff for a subclass, consisting of all persons or entities that acquired Stemline common stock in or traceable to the Offering carried out on January 20, 2017 (the "Offering Subclass"), who are also all members of the Class. Excluded from the Offering

Subclass are Defendants, the officers and directors of the Company at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

86. The members of both the Class and the Offering Subclass are so numerous that joinder of all members is impracticable. Throughout the Class Period, Stemline's securities were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiffs at this time and can only be ascertained through appropriate discovery, Plaintiffs believe that there are hundreds or thousands of members in the proposed Class. Millions of Stemline shares were traded publicly during the Class Period on the NASDAQ, and Stemline offered and sold 4.5 million shares of common stock to the members of the Offering Subclass. As of February 24, 2017, Stemline had 23.659 million common shares outstanding. Record owners and other members of the Class may be identified from records maintained by Stemline or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

87. Plaintiffs' claims are typical of the claims of the members of the Class, as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

88. Plaintiff Marion Beeler's claims are typical of the claims of the members of both the Class and the Offering Subclass, as all members of the Offering Subclass are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

89. Plaintiffs will fairly and adequately protect the interests of the members of the Class and have retained counsel competent and experienced in class actions and securities litigation. Plaintiffs have no interests antagonistic to or in conflict with those of the Class.

90. Plaintiff Marion Beeler will fairly and adequately protect the interests of the members of the Class and the Offering Subclass and has retained counsel competent and experienced in class actions and securities litigation. Plaintiff Marion Beeler has no interests antagonistic to or in conflict with those of the Offering Subclass.

91. Common questions of law and fact exist as to all members of the Class and Offering Subclass and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- (a) whether Defendants violated the federal securities laws as alleged herein;
- (b) whether Defendants' statements to the Class and to the Offering Subclass during the Class Period omitted and/or misrepresented material facts about the business, operations, and prospects of Stemline;
- (c) whether the Individual Defendants caused Stemline to issue false and misleading statements during the Class Period;
- (d) whether Defendants acted knowingly or recklessly in issuing false and misleading statements;
- (e) whether the members of the Class have sustained damages and, if so, what the proper measure of damages is.

92. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class individually to redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

## **VI. PRESUMPTION OF RELIANCE (FRAUD-ON-THE-MARKET DOCTRINE)**

93. The market for Stemline's securities was open, well-developed and efficient at all relevant times. As a result of the materially false and/or misleading statements and/or failures to disclose, Stemline's securities traded at artificially inflated prices during the Class Period. On October 30, 2015, the Company's shares closed at a Class Period high of \$150.94 per share. Plaintiffs and other members of the Class purchased or otherwise acquired the Company's securities relying upon the integrity of the market price of Stemline's securities and market information relating to Stemline and have been damaged thereby.

94. During the Class Period, the artificial inflation of Stemline's shares was caused by the material misrepresentations and/or omissions particularized in this Complaint causing the damages sustained by Plaintiffs and other members of the Class. As described herein, during the Class Period, Defendants made or caused to be made a series of materially false and/or misleading statements about Stemline's business, prospects, and operations. These material misstatements and/or omissions created an unrealistically positive assessment of Stemline and its business, operations, and prospects, thus causing the price of the Company's securities to be artificially inflated at all relevant times, and when disclosed, negatively affected the value of the Company shares. Defendants' materially false and/or misleading statements during the Class Period resulted in Plaintiffs' and other members' of the Class purchasing the Company's securities at such artificially inflated prices, and each of them has been damaged as a result.

95. At all relevant times, the market for Stemline's securities was an efficient market for the following reasons, among others:

(a) Stemline shares met the requirements for listing, and were listed and actively traded on the NASDAQ, a highly efficient and automated market;

(b) Stemline shares have recently traded at an average daily volume of 198,832 over three months;

(c) Stemline was covered by at least five analyst firms: Cowen & Company, Jefferies & Co., Wedbush Securities, H.C. Wainwright & Co., and Ladenburg Thalmann;

(d) Stemline has a market capitalization of \$228.55 million as of June 24, 2017;

(e) As a regulated issuer, Stemline filed periodic public reports with the SEC and/or the NASDAQ;

(f) Stemline regularly communicated with public investors *via* established market communication mechanisms, including through regular dissemination of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services.

96. Evidence will show price impact using the statistically significant Company-specific stock price changes in response to disclosures and/or materializations of previously concealed risks that allegedly corrected the omissions and/or misrepresentations alleged herein.

97. As a result of the foregoing, the market for Stemline's securities promptly digested current information regarding Stemline from all publicly available sources and reflected such information in Stemline's share price. Under these circumstances, all purchasers of Stemline's securities during the Class Period suffered similar injury through their purchase of Stemline's securities at artificially inflated prices, and a presumption of reliance applies.

98. A Class-wide presumption of reliance is also appropriate in this action under the Supreme Court's holding in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972) because the Class's claims are, in large part, grounded on Defendants' material omissions in the face of their duty to disclose the material information of which they were aware or recklessly

disregarded. Because this action involves Defendants' failure to disclose material adverse information regarding the Company's business operations and financial prospects—information that Defendants were obligated to disclose—positive proof of reliance is not a prerequisite to recovery.

## **VII. NO SAFE HARBOR**

99. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this Complaint. The statements alleged to be false and misleading herein all relate to then-existing facts and conditions. In addition, to the extent certain of the statements alleged to be false may be characterized as forward looking, they were not identified as “forward-looking statements” when made, and there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. In the alternative, to the extent that the statutory safe harbor is determined to apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the speaker had actual knowledge that the forward-looking statement was materially false or misleading, and/or the forward-looking statement was authorized or approved by an executive officer of Stemline who knew that the statement was false when made.

## **VIII. CAUSES OF ACTION**

### **COUNT I:**

#### **Violation of Section 10(b) of The Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants**

100. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

101. During the Class Period, Defendants made, disseminated or approved the false and misleading statements specified above. Defendants knew that such statements, when made, were false and misleading, or were reckless in their disregard as to the truth of such statements, which contained material misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

102. Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5 in that they:

- (a) employed devices, schemes, and artifices to defraud;
- (b) made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and/or
- (c) engaged in acts, practices, and a course of business that operated as a fraud or deceit upon Plaintiffs in connection with their purchases of Stemline securities during the Class Period.

103. Plaintiffs have suffered damages in that, in reliance on Defendants' statements and the integrity of the market, they paid artificially inflated prices for Stemline's securities. Plaintiffs would not have purchased such securities at the prices they paid, or at all, if they had been aware that the market prices of such securities had been artificially and falsely inflated by Defendants' misleading statements.

104. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs suffered damages in connection with their purchases of Stemline's securities during the Class Period.



**COUNT II:**

**Violation of Section 20(a) of The Exchange Act Against the Individual Defendants**

105. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

106. The Individual Defendants acted as controlling persons of Stemline within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions, and their ownership and contractual rights, participation in and/or awareness of the Company's operations and/or intimate knowledge of the false financial statements filed by the Company with the SEC and disseminated to the investing public, the Individual Defendants had the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements which Plaintiffs contend are false and misleading. The Individual Defendants were provided with or had unlimited access to copies of the Company's reports, press releases, public filings and other statements alleged by Plaintiffs to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

107. In particular, each of these Defendants had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, is presumed to have had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

108. As set forth above, Stemline and the Individual Defendants each violated Section 10(b) and Rule 10b-5 by their acts and/or omissions as alleged in this Complaint. By virtue of their positions as controlling persons, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of Defendants' wrongful conduct,

Plaintiffs and other members of the Class suffered damages in connection with their purchases of the Company's securities during the Class Period.

**COUNT III:**

**Violation of Section 11 of the Securities Act Against All Defendants**

109. Plaintiff Marion Beeler repeats and reallege each and every allegation contained above.

110. The Offering Documents for the Offering were inaccurate and misleading, contained untrue statements of material facts, omitted to state other facts necessary to make the statements made not misleading, and omitted to state material facts required to be stated therein.

111. Stemline is the registrant for the Offering. Defendants are responsible for the contents of the Offering Documents based upon their status as directors of the Company or because they signed or authorized the signing of the Registration Statement on their behalf pursuant to Sections 11(a)(1)-(3) of the Securities Act.

112. As issuer of the shares, Stemline is strictly liable to Plaintiffs and the Class for the misstatements and omissions.

113. Stemline is strictly liable for the contents of the Offering Documents. Defendants failed to make a reasonable investigation or possess reasonable grounds for the belief that the statements contained in the Offering Documents were true and without omissions of any material facts and were not misleading.

114. By reasons of the conduct herein alleged, each Defendant named in this Count violated Section 11 of the Securities Act.

115. Plaintiff Marion Beeler acquired Stemline shares pursuant to the Offering Documents.

116. Plaintiff Marion Beeler and the Class have sustained damages. The value of Stemline shares has declined substantially subsequent to and due to Defendants' violations.

117. At the times Plaintiffs purchased Stemline shares, Plaintiffs and other members of the Class were without knowledge of the facts concerning the wrongful conduct alleged herein and could not have reasonably discovered those facts prior to the Offering. Less than one year has elapsed from the time that Plaintiffs discovered or reasonably could have discovered the facts upon which this Complaint is based to the time that Plaintiffs filed this Complaint. Less than three years elapsed between the time that the securities upon which this Count is brought were offered to the public and the time Plaintiffs filed this Complaint.

**COUNT IV:**

**Violations of Section 15 of the Securities Act Against Individual Defendants**

118. Plaintiff Marion Beeler repeats and realleges each and every allegation contained above.

119. This claim is asserted against the Individual Defendants, each of whom was a control person of Stemline during the relevant time period.

120. For the reasons set forth in the First Claim, above, Stemline is liable to the Plaintiffs and the members of the Class who purchased Stemline shares in the Offering based on the untrue statements and omissions of material fact contained in the Offering Documents and Prospectus, pursuant to Section 11 of the Securities Act, and were damaged thereby.

121. The Individual Defendants were control persons of Stemline by virtue of, among other things, their positions as senior officers of the Company, and they were in positions to control and did control, the false and misleading statements and omissions contained in the Offering Documents.

122. None of the Individual Defendants made reasonable investigation or possessed reasonable grounds for the belief that the statements contained in the Offering Documents were accurate and complete in all material respects. Had they exercised reasonable care, they could have known of the material misstatements and omissions alleged herein.

123. This claim was brought within one year after the discovery of the untrue statements and omissions in the Offering Documents and within three years after Stemline shares were sold to the Class in connection with the Offering.

124. By reason of the misconduct alleged herein, for which Stemline is primarily liable, as set forth above, the Individual Defendants are jointly and severally liable with, and to the same extent as, Stemline pursuant to Section 15 of the Securities Act.

**COUNT VI:**

**Violation of Section 12(a)(2) of the Securities Act Against Jefferies of the Securities Act  
Against Individual Defendants**

125. Plaintiff Marion Beeler repeats and realleges each and every allegation set forth above, except any allegation of fraud, recklessness or intentional misconduct.

126. This Count is brought pursuant to § 12(a)(2) of the Securities Act on behalf of all persons or entities who purchased Stemline shares pursuant to the Offering Documents.

127. Jefferies was the seller of a security, specifically Stemline common stock.

128. By means of the Offering Documents, Jefferies offered common stock of the Company to the class in return for \$10.00 each. Jefferies's actions of solicitation consisted primarily of the preparation and/or dissemination of the Offering Documents.

129. Jefferies sold Stemline common stock through the use of interstate communication, the use of interstate commerce, and the use of the mails, including the use of a

Prospectus, which contained untrue statements of material fact or omitted to state material facts necessary in order to make the statements made not misleading.

130. Jefferies cannot prove that it did not know, or in the exercise of reasonable care, could not have known, of the untruth or omission described in the preceding paragraph.

131. By reason of the conduct alleged herein, Jefferies violated § 12(a)(2) of the Securities Act. As a direct and proximate result of the Underwriter Defendants' conduct, Plaintiff Marion Beeler and other members of the Offering Subclass who purchased Stemline common stock pursuant to the Offering Documents and traceable thereto have suffered substantial damage. Accordingly, Plaintiff Marion Beeler and the other members of the Offering Subclass were harmed, and seek damages and/or rescission of the IPO.

#### **IX. PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs pray for relief and judgment, as follows:

- A. Determining that this action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure;
- B. Awarding compensatory damages in favor of Plaintiffs and the other Class members against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;
- C. Awarding Plaintiffs and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and
- D. Such other and further relief as the Court may deem just and proper.

**X. JURY TRIAL DEMANDED**

Plaintiffs hereby demand a trial by jury in this Action.

Dated: June 26, 2017

Respectfully submitted,

POMERANTZ LLP

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**SWORN CERTIFICATION OF PLAINTIFF**

**STEMLINE THERAPEUTICS, INC. SECURITIES LITIGATION**

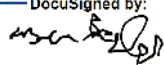
I, Marion Beeler individually, and/or in my capacity as trustee and/or principal for accounts listed on Schedule A, certify that:

1. I have reviewed the Complaint and authorize its filing and/or the filing of a Lead Plaintiff motion on my behalf.
2. I did not purchase **STEMLINE THERAPEUTICS, INC.** the security that is the subject of this action, at the direction of plaintiff's counsel or in order to participate in any private action arising under this title.
3. I am willing to serve as a representative party on behalf of a class and will testify at deposition and trial, if necessary.
4. My transactions in **STEMLINE THERAPEUTICS, INC.** during the Class Period set forth in the Complaint are as follows:  
  
(See attached transactions)
5. I have not served as a representative party on behalf of a class under this title during the last three years, except for the following:
6. I will not accept any payment for serving as a representative party, except to receive my pro rata share of any recovery or as ordered or approved by the court, including the award to a representative plaintiff of reasonable costs and expenses (including lost wages) directly relating to the representation of the class.

I declare under penalty of perjury that the foregoing are true and correct statements.

6/22/2017

Date

DocuSigned by:  
  
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Marion Beeler


**Marion Beeler's Transactions in  
Stemline Therapeutics, Inc. (STML)**

<b>Date</b>	<b>Transaction Type</b>	<b>Quantity</b>	<b>Unit Price</b>
01/20/2017*	Bought	3,000	\$10.8000

\*Purchased pursuant to registration statement/prospectus.



- Inbox (9999+)
- Drafts (22)
- Sent
- Archive
- Spam (141)
- Trash (372)
- Smart Views
- Important
- Unread
- Starred
- People
- Social
- Shopping
- Travel
- Finance
- Folders
- Recent

**AEGIS CAPITAL CORP.**  
810 7TH AVENUE  
18TH FLOOR  
NEW YORK NY 10019

MARIAN B BEELER  
[REDACTED]

ORIGINAL

CONFIRMATION NOTICE

TRANSACTION DATE 01/20/2017	ACCOUNT NUMBER [REDACTED]
SETTLEMENT DATE 01/25/2017	ACCOUNT TYPE [REDACTED]
PROCESSING DATE 01/20/2017	TRANSACTION TYPE 67

WE CONFIRM THE FOLLOWING TRANSACTION(S):

DESCRIPTION	SYMBOL STML	CUSIP 85958C107	YOU BOUGHT				
STEMLINE THERAPEUTICS INC COM SOLICITED SOLD PURSUANT TO REGISTRATION STATEMENT/PROSPECTUS AVAILABLE GO TO WWW.SEC.GOV/EDGAR.SHTML OR BROKER FOR FINAL PROSPECTUS REPORTED PRICE 10.5,							
QUANTITY	PRICE	PRINCIPAL/ GROSS AMOUNT	ACCRUED INTEREST	COMMISSION	MARK UP/DOWN PER SHARE	OTHER FEES/ SERVICE CHARGE	SALES CHARGE RATE
3000	10.80	32400.00	0.00	0.00	0.3000	35.00	0.000%
3000		32400.00	0.00	0.00		35.00	

SUMMARY:

SERVICE CHARGE 35.00

THANK YOU

IMPORTANT TAX INFORMATION

PLEASE RETAIN FOR YOUR RECORDS

PLEASE MAKE CHECKS PAYABLE TO:

RBC CORRESPONDENT SERVICES

SERVICE CHARGE IS ADDITIONAL REVENUE TO

AEGIS CAPITAL CORP. SERVICE CHARGES MAY

VARY BY REPRESENTATIVE AND/OR BRANCH.

NET AMOUNT

32435.00

YOUR FINANCIAL ADVISOR:

[REDACTED]